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K000500

CRITIKON
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February 11, 2000

SUMMARY OF SAFETY AND EFFECTIVENESS
DINAMAP® Advanced NIBP Module

1. Submitter

Critikon Company, L.L.C.
4502 Woodland Corporate Boulevard
Tampa, Florida 33614

2. Company Contact

Thomas English
Director, Regulatory Affairs and Clinical Services

3. Device Name

Trade Name:	DINAMAP® Advanced NIBP Module
Common Name:	Non-Invasive Blood Pressure Module
Classification/ Device Product Code:	Noninvasive blood pressure measurement system- 870.1130, DXN

4. Predicate Device

Advanced NIBP Module-K982641, cleared on 3/29/99, Critikon L.L.C.

DINAMAP MPS *Select Portable* Monitor-K971659, cleared on 9/19/97 Critikon, Div. Of Johnson & Johnson

DINAMAP MPS *Select* Multiparameter System-K955113, cleared on 8/15/96, Johnson & Johnson Medical, Inc.

5. Device Description

Used with the DINAMAP MPS *Select* Family of Monitors, the *DINAMAP® Advanced NIBP Module* obtains systolic, diastolic , mean arterial pressure and pulse rate via the oscillometric method. The *DINAMAP® Advanced NIBP Module* optimizes performance in the presence of artifact due to vibration and patient motion.

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6. Intended Use

The *DINAMAP® Advanced NIBP Module* is designed for use with the DINAMAP® MPS™ Select™ Family of monitors, including the DINAMAP MPS Select Portable Monitor and the DINAMAP MPS Select Multiparameter System. The *DINAMAP® Advanced NIBPModule* is intended to obtain a single patient's systolic, diastolic, mean arterial pressure and pulse rate in the same intended use environment as the DINAMAP MPS Select Family of monitors: hospital, outpatient surgery and healthcare practitioner facilities. The DINAMAP® Advanced NIBP Module combines advanced NIBP for the adult, pediatric and neonate populations. This device is intended for qualified personnel trained in its use.

7. Technological Characteristics

The *DINAMAP® Advanced NIBP Module* has the same technological characteristics as the predicate devices, the Advanced NIBP Module and the DINAMAP MPS Select NIBP Module used in the DINAMAP MPS Select Portable Monitors and the DINAMAP MPS Select Multiparameter System.

8. Clinical Testing

Clinical studies were conducted to demonstrate performance (safety and effectiveness) of the *DINAMAP® Advanced NIBP Module*. The module from a hardware perspective, including environmental and EMC testing, was cleared for marketing with the previously mentioned Advanced NIBP Module(K982641 cleared on3/29/99), the DINAMAP MPS Select Portable(K971569 cleared on 9/19/97), and the DINAMAP MPS Select Multiparameter System (K955113 cleared on 8/15/96).

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Accuracy for the *DINAMAP® Advanced NIBP Module* was established for the adult population with the ANSI/AAMI SP10 clinical study submitted in the Advanced NIBP Module, K982641(cleared on 3/29/99).

Equivalency of the *DINAMAP® Advanced NIBP Module* is established for the pediatric population with a comparison study against the DINAMAP® MPS™ Select™ Monitor, K955113 (cleared on 8/15/96). This study is included in this 510(K) submission.

Accuracy of the *DINAMAP® Advanced NIBP Module* is established for the neonate population in a clinical study according to applicable portions of the ANSI/AAMI SP10 standard. This clinical study is included in this 510(K) submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Critikon Company, L.L.C.
C/O Thomas J. English
4502 Woodland Corporate Blvd.
Tampa, FL 33614

Re: K000500
Trade Name: DINAMAP® Advanced NIBP Module
Regulatory Class: II (Two)
Product Code: DXN
Dated: May 12, 2000
Received: May 17, 2000

Dear Mr. English:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Brian E. Stavenow for

James E. Dillard III
Director
Division Of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(K) Number (if known): K000500

Device Name: *DINAMAP® Advanced NIBP Module*

Indications for Use:

The *DINAMAP® Advanced NIBP Module* is designed for use with the DINAMAP MPS™ *Select*™ Family of Monitors, including the DINAMAP MPS *Select* Portable Monitor and the DINAMAP MPS *Select* Multiparameter System. The *DINAMAP® Advanced NIBP Module* is intended to obtain a single patient's systolic, diastolic, mean arterial blood pressures and pulse rate in the same intended use environment as the DINAMAP MPS *Select* Family of Monitors; hospital, outpatient surgery and healthcare practitioner facilities. The *DINAMAP® Advanced NIBP Module* optimizes performance in the presence of artifact. The *DINAMAP® Advanced NIBP Module* combines Advanced NIBP for the adult, pediatric and neonate populations. The device is intended for qualified healthcare personnel trained in its use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use ____
(per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000500